

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/789,400

**Applicant(s)**

COLLINS ET AL.

**Examiner**

Shin-Lin Chen

**Art Unit**

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 09 September 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
b) ☐ They raise the issue of new matter (see NOTE below);  
c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1, 3-6, 15-19, 25, 26, 58 and 59.

Claim(s) withdrawn from consideration: None.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

/Shin-Lin Chen/  
Primary Examiner, Art Unit 1632

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 103(a) rejection of claims 55 and 56 because claims 55 and 56 have been canceled.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that claim 1, 15 and 16 have been amended to limit the scope of the claims to mutation that ablate expression of the M2-2 protein. Applicants listed 8 GenBank Accession Nos. of HMPV sequences and argue that the disclosed M2-2 nucleotide sequence is sufficiently homologous to those of other HMPV strains to adequately describe the claimed subject matter. The HMPV M2-2 protein is encoded by highly conserved nucleotide sequence from strain to strain and one of skilled in the art would readily identify the M2-2 protein of HMPV by performing sequence analysis and to create an rHMPV having one or more mutations that ablate the expression of the M2-2 protein (amendment, p. 5-7). This is not found persuasive because of the reasons of record. The listed GenBank Accession Nos. of HMPV sequences are published after the effective filing date of the instant invention (2-28-03). AY530089 to AY530094 were published on 1-19-04, DQ843658 was published on 7-10-06 and FJ168779 was published on 8-28-08. None of those sequences were published at the time of the invention. The specification fails to provide the structural features of the variants that one skilled in the art can envision the nucleotide sequence of any other HMPV strain or substrain. No common structural attributes identify the members of the genus. It is apparent that applicants only have possession of the nucleotide sequence of HMPV strain 83 and strain 75 but do NOT have possession of nucleotide sequence of any other HMPV strains or substrains. The nucleotide sequences of SEQ ID Nos. 1 and 2 are insufficient to describe the claimed recombinant HMPVs. Absent possession of the claimed rHMPV other than the disclosed SEQ ID Nos. 1 and 2, one skilled in the art at the time of the invention would not know how to use the claimed rHMPV without undue experimentation. Further, the specification also fails to provide adequate guidance and evidence for whether and what kind of phenotypic change of the rHMPV could be resulted by partial or complete deletion of rHMPV M2-2 ORF or one or more nucleotide substitutions that ablates expression of the M2-2 ORF. One skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.